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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,374	07/11/2001	Steve A. Herweck	ATA-297	8317

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LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER

MATHEW, FENN C

ART UNIT	PAPER NUMBER
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3764

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DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/903,374

Applicant(s)

HERWECK ET AL.

Examiner

Fenn C Mathew

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-9 and 12-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 6, 7, 12-15, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu (U.S. 5,061,276) in view of Lentz (U.S. 6,036,724). Referring to claim 1, Tu discloses a device for surgical implantation comprising a first tube of polymeric material, a membrane of polymer material positioned about the exterior surface of the membrane (col. 5, lines 25-45), to form axially spaced ridges that enable the material to substantially close a hole that is created when the material is punctured, the membrane having a microstructure of nodes interconnected by fibrils effective to facilitate bonding (col. 7, lines 5-20). Tu discloses the claimed invention except for the feature of having the outer membrane wrapped about the exterior of the first tube but rather teaches the outer layer as a coating or film. Lentz discloses an analogous device, and in column 6, lines 24-40 teaches that one can alternatively wrap a membrane helically around the tube in lieu of using a film. Therefore it would have been obvious to one having ordinary skill in the art at the time of invention to have the outer membrane of Tu wrapped around the first tube as taught by Lentz as an art-recognized alternative.
3. Referring to claim 6, Tu discloses the nodes being perpendicular to the direction of expansion. Inherently the nodes are oriented at an angle other than 0 degrees with respect to the wound support structure (col. 8, lines 20-26).

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4. Referring to claim 7, Tu discloses the claimed invention except for the specific angle of the nodes with respect to the winding axis. The feature of having the nodes at a 90-degree angle with respect to the winding axis is considered a matter of simple design choice within the knowledge of the skilled artisan as it appears no stated problem is solved, nor is any inherent advantage gained, and the configuration of the modified Tu device would perform equally well.

5. Referring to claim 12, Tu discloses the claimed method except for the step of wrapping the membrane of polymer material around the tube. As discussed above, Lentz discloses that it is an art-recognized alternative to wrap the polymer material around the tube.

6. Referring to claims 13-15 and 19, Tu as modified by Lentz teaches the membrane being wrapped helically or spirally around the tube and capable of being wound upon a helical or spirally shaped winding axis of the support structure.

7. Referring to claims 20-21, Tu as modified by Lentz above teaches the first tube having an interior surface defining a lumen.

8. Claims 2-3, 5, 8-9, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu in view of Lentz as applied to claim 1 above, and further in view of Martakos (U.S. 5,897,587). Referring to claim 2, Tu, as modified above discloses the claimed invention except for the specific material of the support structure. The feature of having the support structure made of metal wire is a design consideration within the level of one with ordinary skill in the art as evidenced by Martakos who teaches an

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analogous device wherein the support structure comprises metal wire. (Column 6, lines 34-35).

9. Referring to claim 3, the modified Tu device discloses the claimed invention except for a support covering. Martakos discloses an analogous device having a support covering (30). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the invention of Tu with a support covering as taught by Martakos in order to provide a protective covering.

10. Referring to claim 5, the modified Tu device discloses the claimed device except for coalescing the first and second tubes and the support structure. Martakos teaches an analogous device, and further teaches coalescing the recited structures using heat (claim 5). It would have been obvious to one having ordinary skill in the art at the time of invention to coalesce the recited structures with heat as taught by Martakos in order to facilitate bonding between the structures.

11. Referring to claims 8-9, Tu discloses the claimed invention including a membrane formed from a polymer material having a microstructure of nodes interconnected by fibrils with a porosity that is less than that of the first tube. Martakos discloses an analogous device and discloses the nodes of the membrane being smaller than the nodes of the first tube, and specifically that the nodes of the membrane are at least 10% smaller than the nodes forming the first tube. (Column 3, lines 4-10). It would have been obvious to one having ordinary skill in the art at the time of invention to have the nodes of the membrane be smaller than the nodes of the first tube in order to provide a lower porosity for the membrane.

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12. Referring to claim 18, Tu discloses the claimed invention except for the specific material of the support structure. The feature of having the support structure made of a bead of ePTFE wire is a design consideration within the level of one with ordinary skill in the art as evidenced by Martakos who teaches an analogous device wherein the support structure comprises a bead of ePTFE.

13. Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu in view of Lentz as applied to claim 1 above, and further in view of Von Albertini (U.S. 4,670,008). The modified Tu is silent with regards to the relationship between the outer diameter of a needle and the space between ridges but does teach that it is preferable to have the diameter of the support structure range from 20-50 microns (col. 11, lines 17-19), and have the support structure wound at the rate of 4-10 per centimeter (col. 18, lines 55-57). Von Albertini teaches needles used for injection and drawing blood, and specifically states that it is well known in the art to have a needle diameter of 1.6-2.2 mm. Therefore it would have been obvious to the skilled artisan to use a needle with a diameter in the above mentioned range, and furthermore, a support structure with a diameter of 50 microns and wound at the rate of 4 per centimeter would have a space between the ridges that was approximately 1.225 times a 1.6 mm diameter needle.

Response to Arguments

14. Applicant's arguments with respect to claims 1-3, 5-9, and 12-21 have been considered but are moot in view of the new ground(s) of rejection. Furthermore, applicant's arguments regarding 7 are not persuasive. Applicant's arguments have

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amounted to a mere allegation of patentability, and have failed to provide any argumentative evidence towards the criticality of the claimed feature. As such, the rejection stands. With respect to the use of Von Albertini, Examiner points out that applicant has not provided any limiting language with respect to the needle. Von Albertini is used to disclose the state of injectable needles, and is relied upon solely for dimensions. Furthermore, Von Albertini speaks of the status of the art, and specifically cites that needles may be used for drawing of blood from arteries, blood vessels, or the like.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fenn C Mathew whose telephone number is (703) 305-2846. The examiner can normally be reached on Monday - Friday 9:00am - 5:30pm.


The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 18, 2004


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